UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ET AL. ex rel. TIMOTHY LEYSOCK, Plaintiff, vs. FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC. Defendants.	No. 12–CV–11354 (FDS) Judge F. Dennis Saylor

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED *QUI TAM* COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

Defendants Forest Laboratories, Inc. ("Forest Labs") and Forest Pharmaceuticals, Inc. ("FPI") (together, "Forest" or "Defendants") respectfully submit this memorandum of law in support of their motion to dismiss the Second Amended Complaint ("SAC")[1] for failure to state a claim, Fed. R. Civ. P. 12(b)(6), and failure to plead fraud with particularity. Fed. R. Civ. P. 9(b).

I. PRELIMINARY STATEMENT

The SAC alleges that Forest has defrauded the Medicare program by knowingly causing the presentment of billions of dollars of "false claims" for reimbursement of prescriptions of Namenda®, an FDA-approved medication sold by Forest for the treatment of moderate to severe Alzheimer's Disease. Specifically, the SAC alleges that Forest sales representatives marketed Namenda to physicians for the "off-label" treatment of mild forms of Alzheimer's Disease ("AD"), a use that purportedly was not "medically accepted" and not reimbursable by Medicare. The SAC further alleges that this purported off-label marketing led Forest to breach the terms of a Corporate Integrity Agreement ("CIA") with the federal government, with the result that *all* prescriptions written for a Medicare beneficiary since September 2010 lead to "false" claims—including prescriptions for the drug's FDA-approved use.

Relator's theories fail on multiple grounds. ***First***, the SAC fails to plead a plausible theory that the alleged breach of Forest's CIA caused the submission of false claims for the simple reason that the CIA does not condition reimbursement of Forest drugs on compliance with its terms. ***Second***, the SAC fails to plead a false claim or a knowing violation with particularity as required by Rule 9(b). The SAC does not identify a single eligible claim for reimbursement that was actually submitted to a Medicare plan. This omission is particularly

[1] Attached as Exhibit 1 to the Declaration of J. Robert Abraham in Support of Defendants' Motion to Dismiss the Second Amended *Qui Tam* Complaint ("Abraham Decl."). All references herein to "SAC" refer to Exhibit 1.

fatal in light of the manner in which the Medicare prescription drug program is administered—managed by private contractors, participation is voluntary and enrollees frequently are responsible for payment themselves due to coverage limitations. Relator also relies solely on allegations of off-label promotion and off-label prescribing in an unsuccessful attempt to raise an inference of fraud. Courts have repeatedly rejected the sorts of generalized and speculative allegations contained in the SAC, and this Court should reject them as well.

For these and the other reasons stated below, the SAC should be dismissed and such dismissal should be with prejudice because Relator has amended his complaint twice and further amendment would be futile. Indeed, it is notable that all named government entities have *declined to intervene* in this action (including the U.S. government and 28 States).[2]

II. STATEMENT OF FACTS AND ALLEGATIONS[3]

A. FEDERAL FOOD, DRUG, AND COSMETIC ACT

The U.S. Food and Drug and Administration ("FDA"), pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, is charged with approving pharmaceutical drugs prior to their introduction into interstate commerce. *Id.* § 355(a). The FDA approves drugs for specific medical uses (also known as "indications"). *Id.* §§ 352, 355(d); *see also* SAC ¶ 32–34. Pharmaceutical manufacturers are permitted to market their drugs for FDA-approved uses to physicians and the public, but are not permitted to market unapproved uses (also known as "off-label" uses). 21 U.S.C. §§ 331(a), (d) & 352(a); *see also Wash. Legal Found. v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2000). The FDA does not regulate the

[2] Furthermore, "unlike *qui tam* relators, when the government . . . intervenes in a *qui tam* action, [the court] may assume that it does not do so solely to use the discovery process as a fishing expedition . . . ." *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 & n. 17 (4th Cir. 2006).

[3] The complaint's well-pleaded factual allegations are accepted as true solely for purposes of this motion, except to the extent they are contradicted by documents cited in the complaint. *See Clorox Co. P.R. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 32 (1st Cir. 2000).

practice of medicine, however, and physicians are free to prescribe drugs—and frequently do so––for any purpose they deem appropriate in their medical judgment, regardless of whether the use is off-label. 21 U.S.C. § 396; *see also Wash. Legal Found.*, 202 F.3d at 333 ("[I]t is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties.").

B. MEDICARE PART D PROGRAM

Medicare Part D is an optional prescription drug coverage plan for Medicare beneficiaries that went into effect in 2006. *See* 42 U.S.C. § 1395w *et seq; see also Omnicare Inc. v. UnitedHealth Grp., Inc.*, 594 F. Supp. 2d 945, 948–49 (N.D. Ill. 2009) (describing Medicare Part D). Under this program, Medicare beneficiaries may (but need not) opt to obtain prescription drug coverage by enrolling in a Prescription Drug Plan or Medicare Advantage Plan, which are plans administered by private contractors and subsidized by the federal government ("Part D Plans"). *See Omnicare*, 594 F. Supp. 2d at 949 & n.1. To participate in the Part D program, private contractors submit bids to Medicare with their proposed formularies and coverage terms, along with actuarial estimates of cost on an annual basis. *See* 42 U.S.C. § 1395w–111.[4] Part D Plans charge enrollees a monthly premium and require drug co-payments. *See id*. § 1395w–115. They may also require an annual deductible before coverage begins, *id*. § 1395w–102(b)(1), and also contain a significant annual coverage gap—commonly referred to as the "donut hole"—during which enrollees are solely responsible for the cost of their prescription drugs.[5] In 2009,

[4] The Center for Medicare and Medicaid Services ("CMS") reports that in 2006, there were 3,103 Part D Plans available. That number increased to 3,415 in 2013. *See* Abraham Decl. Ex. 2 (CMS 2013 Medicare Part D Landscape (Sept.19, 2012), at 11). The court may take judicial notice of this publicly available government report. *See, e.g., Rahman v. Schriro*, No. 13–CV–6095 (CS), 2014 WL 2208050, at *3 (S.D.N.Y. May 27, 2014) (taking judicial notice of government publication).

[5] Specifically, once an enrollee's drug costs reach a certain threshold each year, Medicare ceases providing coverage and the enrollee must pay the full cost of his or her prescription drugs until an out-of-pocket limit is reached, at which time catastrophic coverage begins and Medicare pays 95% of

approximately 3.4 million enrollees reached the coverage gap, which means Medicare did not subsidize any of their drug costs during the gap period. *See* Abraham Decl. Ex. 6 (Kaiser Family Foundation Medicare Policy, Understanding the Effects of the Medicare Part D Coverage Gap in 2008 and 2009 (2011), at ii)) [hereinafter "Kaiser Coverage Gap Study"].[6]

By statute, the Medicare Part D program reimburses enrollees' use of "covered Part D drugs." 42 U.S.C. § 1395w–102(b). A covered Part D drug is defined as any drug that is approved by the FDA and used for a "medically accepted indication." *Id.* §§ 1395w–102(e)(1) & (e)(4)(A)(ii). A medically accepted indication is defined to include on-label uses as well as off-label uses supported by citation in an identified drug compendium. *Id.* §§ 1395w–102(e)(1) & (e)(4)(A)(ii).[7] Enrollees' claims for payment of prescription medications are submitted to their Part D Plans, which administer coverage pursuant to the terms of the individual plan in accordance with Medicare Part D guidelines. Although Medicare subsidizes the operations of Part D Plans, each plan is responsible for processing individual claims. *See, e.g.* 42 U.S.C. §§ 1395w–112(b)(4)(A) & (b)(5) (providing that Part D Plan sponsors pays enrollee claims and claims for reimbursement submitted by pharmacies); 42 C.F.R. §§ 423.636 (a)(2) & (b)(2) (providing that Part D Plan sponsors authorize and pay covered benefits)*;* s*ee also* Abraham

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drug costs for the remainder of the year. *See* 42 U.S.C. §§ 1395w–102(b)(2)(C), (b)(3)–(4) & 1395w–102(b)(4)(A); s*ee also* Abraham Decl. Ex. 2 (Medicare Payment Advisory Commission, Part D Payment System (Oct. 2013), at 2) [hereinafter Medicare Payment Advisory Comm'n] (describing Medicare Part D subsidies and coverage gap). Pursuant to the Affordable Care Act, the coverage gap began to be phased out in 2011, with complete phase-out to occur by 2020. Abraham Decl. Ex. 2 (Medicare Payment Advisory Comm'n at 1 & n.3); *see also* 42 U.S.C. § 1395w–114a.

6 The court may take judicial notice published reports and studies that are publicly available. *See, e.g., Biotechnology Value Fund, L.P. v. Celera Corp.*, No. C 13–03248 WHA, 2014 WL 988913, at *2 (N.D. Cal. Mar. 10, 2014) (taking judicial notice of university study).

7 There is authority for the proposition that Medicare may also reimburse off-label, non-compendium uses of covered Part D drugs. *See Layzer v. Leavitt*, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011) (holding Part D coverage not limited to FDA-approved and compendia-supported uses).

Decl. Ex. 3 (Medicare Payment Advisory Commission, Part D Payment System (Oct. 2013)) (describing subsidization of Part D plans).

C. NAMENDA

Namenda (generic name memantine hydrochloride) is a prescription drug manufactured and sold by Forest. SAC ¶ 1. In 2003, Namenda was FDA-approved as a safe and effective treatment for moderate to severe AD. *Id.* ¶ 3. Only two other drugs are FDA-approved for this indication, Namenda XR[8] and Aricept.[9] In November 2004, Forest submitted an application to the FDA seeking approval to market Namenda for the treatment of mild AD. *Id.* ¶ 6. In June 2005, the FDA denied Forest's application, concluding there was insufficient evidence at the time of Namenda's efficacy for that use. *Id.* ¶ 7.

D. FOREST'S CORPORATE INTEGRITY AGREEMENT

In September 2010, Forest entered into a resolution of investigations conducted by the U.S. Department of Justice into the marketing of certain drugs. SAC ¶ 43. In connection therewith, Forest entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG"). The CIA requires that Forest maintain its current Compliance Program and undertake a set of defined corporate integrity obligations. Among these is a requirement that Forest's Chief Compliance Officer submit an annual certification stating that, to the best of his or her knowledge, Forest is in compliance with FDA and federal health care program requirements and other CIA obligations. *Id.* Ex. E at 49–50 (attaching Forest CIA). Forest is also required to report certain "Reportable Events," including matters a reasonable person would consider a probable violation

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[8] The extended release form of Namenda.

[9] *See* National Institute on Aging, *Alzheimer's Disease Medications Fact Sheet*, NIH Publication No. 08–3431 (Jan. 2014), *available at* http://www.nia.nih.gov/alzheimers/publication/alzheimers-disease-medications-fact-sheet.

of law. *Id*. at 26–27. In the event of a "material breach," which includes failing to report a Reportable Event and take corrective action, OIG may seek to exclude Forest from future participation in federal health care programs after providing an opportunity to cure. *Id.* at 56–57.

E. RELATOR'S CLAIMS

Relator Timothy Leysock ("Relator") was employed by Forest as a sales representative from 1996 through 2012. SAC ¶ 14. Relator alleges that, beginning in 2006, Forest sales managers instructed sale representatives to promote Namenda during conversations with physicians using three allegedly off-label messages: (*i*) Namenda is an effective treatment for all three stages of AD (mild, moderate, and severe); (*ii*) Namenda does not have the harsh gastrointestinal ("GI") side-effects of Aricept, a different AD treatment, and (*iii*) Namenda is GI-protective, so physicians treating patients with AD should prescribe Namenda first before prescribing Aricept. *Id.* ¶ 57. Relator asserts that the use of Namenda to treat mild AD is not "medically accepted" and therefore not eligible for reimbursement by Medicare, and, as a result, all prescriptions of Namenda written for a Medicare beneficiary for mild AD since 2006 as a result of the purported off-label messages led to "false claims." *Id.* ¶¶ 36–39, 42.

Relator further alleges that Forest breached the terms of its CIA by submitting allegedly false annual "certifications that it is in compliance with Federal health care program requirements and FDA requirements, and the obligations of the CIA." *Id.* ¶ 45. The SAC incorrectly describes the CIA's certification requirement, which in reality is limited to a single certification from the Chief Compliance Officer as described above. Relator contends that Forest's compliance with the CIA was "material to the Government's decision to pay claims for Forest medications," *id.* ¶ 46, and that Forest's failure to report the alleged off-label promotion as a "Reportable Event" breached the CIA, with the result that *all* Namenda prescriptions written for Medicare beneficiaries since September 2010—even for on-label uses—led to "false" claims.

The SAC also purports to identify eight physicians who allegedly "relied" on Forest sales representatives' off-label marketing messages when prescribing Namenda to a Medicare beneficiary diagnosed with mild AD. *Id.* ¶¶ 86–156. The SAC does not allege that any of the eight Medicare beneficiaries was enrolled in a Part D Plan or that any of the alleged prescriptions were eligible for Part D coverage. The SAC also does not allege that Forest made any misrepresentations in connection with the promotion of Namenda to these eight physicians, and acknowledges that each of them knew they were prescribing Namenda for an off-label use. *Id.* ¶¶ 94, 103, 113, 121, 128, 136, 145, 154. The SAC does not allege that these physicians would not have prescribed Namenda in the absence of the alleged off-label messages, or that the alleged messages were material to the physicians' decision to prescribe the drug. Finally, Relator does not contend that Forest offered any kickback, benefit, or other inducement to these physicians in connection with their prescribing of Namenda.

F. PROCEDURAL HISTORY

Relator initiated this lawsuit by filing a *qui tam* complaint under seal on July 24, 2012, followed by an amended complaint on October 2, 2012. SAC ¶ 23. On April 16, 2014, after almost two years of investigation, the U.S. Government notified the Court that it would not intervene in this action and requested that the complaint be unsealed.[10] The SAC was filed and unsealed on April 30, 2014.[11] On May 19, 2014, the remaining named Government entities (28

[10] Notice of Election to Decline Intervention, *U.S. ex rel. Leysock v. Forest Labs., Inc.*, 12–CV–11354 (FDS) (D. Mass. Apr. 16, 2014) (DE 23).

[11] Order, *U.S. ex rel. Leysock v. Forest Labs., Inc.*, 12–CV–11354 (FDS) (D. Mass. Apr. 30, 2014) (DE 26).

states and the District of Columbia) notified the Court that they too were declining to intervene in the action.[12] Defendants now move to dismiss the SAC in its entirety.

III. ARGUMENT

To survive a motion to dismiss, Relator must plead a claim for relief that is "plausible on its face," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), including facts that "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 2012 WL 5398564, at *3 (D. Mass. Nov. 1, 2012), *aff'd*, 737 F.3d 116 (1st Cir. 2013) (Saylor, J.). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice to" plead a claim. *Iqbal*, 556 U.S. at 678. As such, Relator must allege facts establishing "more than a sheer possibility that a defendant acted unlawfully," *id.*, and dismissal is warranted where the complaint does not "possess enough heft to show that [Relator] is entitled to relief." *Ge*, 2012 WL 5398564, at *3 (*quoting Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2009)). Where, as here, the complaint is based on allegations of fraud, Relator must plead the elements of his claims with particularity as required by Federal Rule of Civil Procedure 9(b).

The SAC fails to state a claim for relief on the theory that Forest violated the CIA for the simple reason that compliance with the CIA's terms is not a precondition for payment. The SAC also fails to plead its claims with the particularity required by Rule 9(b) because it fails to adequately plead the existence of a false claim or that Forest knowingly caused or conspired to cause the submission of a false claim. For these and the other reasons stated below, the SAC should be dismissed.

[12] Notice of Election to Decline Intervention and Dismissal of Certain Commonwealth and State False Claims Act Claims, *United States ex rel. Leysock v. Forest Labs., Inc.*, 12–CV–11354 (FDS) (D. Mass. May 19, 2014) (DE 38).

A. ALLEGED NON-COMPLIANCE WITH FOREST'S CIA DOES NOT RENDER CLAIMS FOR REIMBURSEMENT OF NAMENDA "FALSE"

Relator alleges that Forest breached its CIA, and therefore all prescriptions of Namenda written for a Medicare beneficiary (both on-label and off-label) since September 2010 led to "false" claims. Even assuming Forest breached the CIA—which it did not—such a breach would not render claims submitted for Medicare reimbursement false or fraudulent because compliance with the CIA is not a precondition of payment.

To establish liability under the False Claims Act ("FCA"), a plaintiff must demonstrate that the defendant knowingly "present[ed], or cause[d] to be presented a false or fraudulent claim for payment," 31 U.S.C. § 3729(a)(1)(A) (emphasis added), or made, used, or caused to be made or used "a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B) (emphasis added). A false or fraudulent claim is "the *sine qua non*" of an FCA violation. *U.S. ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 225 (1st Cir. 2004) (internal quotations omitted). Claims are only false or fraudulent if preconditions of payment are not satisfied. *See, e.g., New York v. Amgen Inc.*, 652 F.3d 103, 110–11 (1st Cir. 2011) ("Relator must show that the claims at issue . . . misrepresented compliance with a material condition of [government] payment such that they were false or fraudulent."); *Ge*, 2012 WL 5398564, at *5–6 (holding FCA claims turn on whether "claims at issue were false or fraudulent—that is, whether the claims misrepresented compliance with a material precondition of payment").

Forest's CIA contains a number of provisions designed to promote compliance with FDA and federal healthcare program requirements relevant to drug promotion and distribution, including mandatory employee training, establishment of policies, and auditing and monitoring activities. *See* SAC Ex. E. Annually, Forest is required to submit to OIG a report describing the measures Forest has undertaken during the preceding year to fulfill the CIA's requirements,

along with a certification by the Chief Compliance Officer that, "to the best of his or her knowledge . . . Forest is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA." *Id*. at 45–50.

The CIA contains a detailed section on "Breach and Default Provisions" and the consequences thereof, including stipulated penalties for failure to implement certain CIA provisions (*e.g*., failure to appoint a Chief Compliance Officer or to establish a written Code of Conduct"). *Id*. at 53–59. In the event of a material breach, OIG may seek to exclude Forest from future participation in federal health care programs.[13] *See id*. at 56. In such circumstances, OIG is required to issue a notice of intent to exclude, and Forest is provided with 30 days to cure the alleged breach. *See id*. at 56–57. A determination to exclude by OIG is subject to review by an Administrative Law Judge and administrative appeal. *See id*. at 57–59.

Nowhere does the CIA condition reimbursement of Forest drugs on compliance with the CIA. Indeed, such a provision would be anathema to the very purpose of the CIA, which is to ensure that Forest drugs *continue* to be reimbursable unless and until OIG makes a determination to exclude Forest from future participation in federal health care programs. Numerous courts have recognized that compliance with the conditions of participation in a federal health care program does not constitute a precondition of payment for prescriptions of the manufacturer's products. *See, e.g., U.S. ex rel. Vigil v. Nelnet, Inc*., 639 F.3d 791, 799–80 (8th Cir. 2011) (dismissing FCA claims where compliance failure jeopardized "continued participation" in federal program but not payment of claims); *U.S. ex rel. Hartwig v. Medtronic, Inc*., No. 3:11cv413–CWR–LRA, 2014 WL 1324339, at *11–12 (S.D. Miss. Mar. 31, 2014) (collecting cases and dismissing FCA claims where conduct related to "condition of participation in

[13] Exclusion means that a manufacturer's products will no longer be eligible for reimbursement. *See* 42 C.F.R. § 1001.1901.

Medicare enforced through administrative mechanisms," not "condition of payment"); *Maa v. Ostroff*, No. 12–CV–00200–JCS, 2013 WL 1703377, at *18–19 (N.D. Cal. Apr. 19, 2013) (dismissing FCA claims where false statement was not material to government's decision to pay claim submitted to Medicare, but instead was relevant to Medicare "conditions of participation"); *see also Ge*, 2012 WL 5398564, at *5–6 (dismissing FCA claims where compliance with adverse-event reporting requirements was not "material precondition of payment").

Because the SAC fails to state a claim for relief under the theory that Forest breached its CIA, this claim should be dismissed or the related allegations in the SAC stricken (¶¶ 43–47). *See* Fed. R. Civ. P. 12(f); *see also Berglund v. Boeing Co., Inc.*, No. 02–193–AS, 2006 WL 1805965, at *9 (D. Or. June 22, 2006) (striking allegations from complaint which were insufficient to support FCA claim).

B. THE SAC FAILS TO PLEAD FRAUD CLAIMS WITH PARTICULARITY UNDER RULE 9(b).

The SAC should be dismissed in its entirety for the independent reason that it fails to plead its fraud claims with particularity as required by Fed. R. Civ. P. 9(b). *See U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007).[14] Specifically, the SAC does not adequately plead the existence of a false claim, or that Forest knowingly caused the submission of a false claim or made a false statement in order to get a false claim paid. 31 U.S.C. § 3729.

1. The SAC Fails to Plead a False Claim with Particularity

Despite making allegations regarding the diagnosis and prescription of Namenda for eight unnamed patients, the SAC alleges in only conclusory terms the existence of an actual false

[14] This heightened pleading requirement serves several purposes particularly relevant to FCA claims, including discouraging strike suits and fishing expeditions. *See, e.g., Karvelas*, 360 F.3d at 231 ("[A] *qui tam* relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery."); *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996).

claim submitted for government reimbursement. In fact, the manner in which the Medicare Part D Program is administered demonstrates that Relator's allegations consist wholly of speculation and over-generalizations.

"When inducement, rather than direct submission, of [false] claims is alleged, a relator must, at a minimum, 'provid[e] factual or statistical evidence to strengthen the inference of fraud beyond possibility . . . .'" *Ge*, 2012 WL 5398564, at *4 (*quoting Rost*, 507 F.3d at 730); *see also U.S. ex rel. Duxbury v. Ortho Biotech Prods*., L.P., 579 F.3d. 29–30 (1st Cir. 2009); *U.S ex rel. Worsfold v. Pfizer, Inc.*, No. 09–11522–NMG, 2013 WL 6195790, at *6 (D. Mass. Nov. 22, 2013) (dismissing claims lacking particular details of scheme combined with reliable indicia raising "strong inference" false claims were submitted).

The SAC purports to identify eight unnamed patients diagnosed with mild AD who were "Medicare beneficiar[ies]" and whose off-label Namenda prescriptions were filled and "presented to the Medicare program for payment." SAC ¶¶ 97, 107, 115, 122, 130, 139, 148, 156. For one unnamed patient, the SAC alleges that a prescription was filled at a CVS Pharmacy in Wilmington, California, at some time between June 2013 and February 2014. *Id.* ¶ 95. These conclusory assertions are the extent of the detail offered to support the existence of false claims. Nowhere does the SAC provide the essential details of an actual claim, including identifying a claim submitted by a Part D Plan enrollee who was eligible for Part D coverage, or the dollar amount or specific date of such a claim. *See, e.g.*, *Worsfold*, 2013 WL 6195790, at *7 (noting plaintiff typically must plead the date, location, content, and amount of false claim); *U.S. v. Infomedics, Inc.*, 847 F. Supp. 2d 256, 263–64 (D. Mass. 2012) (same).

The SAC's conclusory allegations are particularly deficient in light of the manner in which the Medicare Part D Program is administered. The realities of Part D establish that the

SAC alleges at most a mere *possibility* that false claims *could* have been submitted, which is not sufficient to plead a false claim with particularity. *See, e.g., U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (dismissing FCA claims and holding relator failed to satisfy Rule 9(b) where complaint alleged a scheme that conceivably might have resulted in submission of false claims but did not cite an actual false claim).

First, Medicare Part D is a voluntary program. *See Omnicare*, 594 F. Supp. 2d at 948–49. The mere fact that a patient is a "Medicare beneficiary" does not mean he or she is automatically enrolled in Medicare Part D. In fact, as of 2013, over 16 million Medicare beneficiaries received prescription coverage through their employer or some other non-Medicare source, or had no prescription drug coverage at all. *See* Abraham Decl. Ex. 4 (Kaiser Family Foundation, Fact Sheet: The Medicare Part D Prescription Drug Benefit (Nov. 2013), at 1–2). The SAC's bare bones suggestion that the Namenda prescriptions written for the eight patients were paid by Medicare simply because the patients were "Medicare beneficiaries" is grossly deficient. The SAC fails to allege that any of the eight patients were enrolled in the Medicare Part D program or to identify which Part D Plan they were enrolled in. *See, e.g., U.S. ex rel. Palmieri v. Alpharma, Inc.*, No. ELH–10–1601, 2014 WL 1168953, at *10 (D. Md. Mar. 21, 2014) (noting inference in context of Medicare Part D that "where a government-insured patient receives a prescription, that prescription must have been filled and a claim for reimbursement must have been submitted to the government" has been "expressly rejected").

Second, Medicare Part D only provides reimbursement up to an annual drug coverage limit. 42 U.S.C. § 1395w–102(b)(3)(A). The resulting coverage gap, commonly referred to as the "donut hole," creates a zone in which Medicare Part D does not provide any reimbursement for the cost of an enrollee's prescription drugs. *See, e.g., Kopstein v. Independence Blue Cross*,

339 F. App'x 261, 262 n.1 (3d Cir. 2009) (explaining Medicare Part D coverage gap). This is particularly relevant in the context of patients with AD, who are most likely to fall within the drug coverage gap due to the costs of their prescription drugs. *See, e.g.*, Abraham Decl. Ex. 5 (AARP Public Policy Institute, Closing a Gap in Medicare Drug Coverage: How to Help Millions of Beneficiaries Afford Needed Medication, at 2) (citing 2007 study finding 64% of AD patients reached coverage gap).[15] The SAC fails to allege any facts to show that, even assuming the eight patients were enrolled in a Part D Plan, their prescriptions were eligible for coverage. The so-called donut hole "illustrates why a prescription provided to a Medicare patient does not necessarily result in the submission of a reimbursement claim to the government." *Palmieri*, 2014 WL 1168953, at *10–11.

The gross over-generalizations in the SAC are reflected in its assertion that some 95% of AD patients are "over 65 and on Medicare," SAC ¶ 11, and thus "almost every prescription of Namenda was presented to the Medicare program." *Id.* ¶ 12. In light of the way Part D coverage actually operates, the SAC's conclusory allegations fall far short of alleging an actual false claim with the required particularity. *See, e.g., U.S. ex rel. Keeler v. Eisai, Inc.*, Nos. 13–10973, 13–11949, 2014 WL 2595592, at *11–12 (11th Cir. June 11, 2014) (dismissing FCA claims where relator "proferr[ed] only conclusory assertions based on his own speculation that claims were submitted" for reimbursement to Medicare Part D).

The SAC also attempts to establish an inference that false claims were submitted by presenting several additional "statistics." The SAC alleges that, as of 2012, Namenda constituted 36% of prescriptions written to treat all stages of AD, SAC ¶ 9, and that an unidentified survey indicates that 60% of physicians who prescribe Namenda off-label do so in reliance on Forest's

[15] *See also* Abraham Decl. Ex. 6 (Kaiser Coverage Gap Study at iii, 6, 12).

allegedly off-label marketing. *Id*. ¶¶ 203–04. At most, such allegations suggest evidence of off-label *prescriptions;* they do not, however, allege actual false claims for government reimbursement with particularity. Numerous courts, including this one, have recognized that allegations of off-label promotion are insufficient to satisfy a plaintiff's burden of pleading the submission of a false claim. *See, e.g., U.S. ex rel. Nathan v. Takeda Pharm. N. Am. Inc.*, 707 F.3d 451, 461 (4th Cir. 2013) (affirming dismissal of FCA claims and rejecting argument that false claims must have been presented to government because "federally insured patients received off-label prescriptions" as "inherently speculative in nature"); *Rost*, 507 F.3d at 733 (dismissing FCA claims where complaint alleged off-label promotion but did not "establish that false claims were submitted for government payment in a way that satisfied the particularity requirement"); *Palmieri*, 2014 WL 1168953, at *10–11 (dismissing FCA claims where relator alleged mere possibility that false claims were submitted to Medicare Part D as result of off-label promotion, despite identifying particular physicians who wrote off-label prescriptions for specific patients who were Medicare beneficiaries); *Worsfold*, 2013 WL 6195790, at *7–9 (dismissing FCA claims where complaint put forth conclusory allegations of off-label promotion and use at specific medical facilities but did not allege more than possibility of false claims); *Infomedics*, 847 F. Supp. 2d at 263–64 (dismissing FCA claims where relator "provided no factual allegations" or "reliable statistical evidence" to establish false claims were ultimately submitted); *Ge*, 2012 WL 5398564, at *6 (dismissing state-law FCA claims for failure to plead with specificity details of any claims for reimbursement); *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:1–CV–00962–WSD, 2012 WL 8020674, at *13 (N.D. Ga. Aug. 29, 2012) (dismissing FCA claims where relator alleged "details of the *filling* of 'off-label' [drug] prescriptions" but "offer[ed] no information on the subsequent submission of reimbursement

claims for . . . those prescriptions"); *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 354–55 (D. Mass. 2011) (dismissing FCA claims where relator's statistical citations did not account for realities of medical device context); Abraham Decl. Ex. 7 (Transcript of Proceedings at 94:11–102:8, *Wilson v. Bristol Myers Squibb, Inc.*, No. 06–CV–12195–MLW (D. Mass. Feb. 7, 2013)) (dismissing FCA claims where relator failed to plead facts or statistical evidence sufficient to allege false claims with particularity).

2. The SAC Fails to Allege With Particularity That Defendants Knowingly Caused the Submission of A False Claim

The SAC also fails to allege with particularity that Forest knowingly caused the submission of a false claim or made a false statement to get a false claim paid. A defendant acts "knowingly" if it acts with "actual knowledge," "in deliberate ignorance of the truth," or "in reckless disregard of the truth." 31 U.S.C. § 3729(b)(1)(A). Relator includes a mere boilerplate assertion that Forest "knowingly and foreseeably caused claims for Namenda to be presented in violation of government conditions of payment," along with other conclusory allegations. SAC ¶ 42. These assertions are undermined by the SAC itself, which contradicts any notion that Forest's alleged off-label promotion "caused" false claims by polluting the independent medical judgment of prescribing physicians.

The SAC suggests that Forest acted "knowingly" because it allegedly continued to market Namenda off-label after entering into the CIA; that certain Forest employees had a practice of not "discuss[ing] Forest's off-label marketing program by text or e-mail," SAC ¶ 61; and that Forest's goal was to achieve sales parity with competitor Aricept. *Id.* ¶¶ 42–47, 57–64. At best, these allegations suggest that Forest knowingly sought off-label prescriptions[16]—an

[16] *See, e.g.*, SAC ¶ 61 (alleging Namenda sales targets are "further corroboration that [Forest] *knowingly directed [its] sales reps to market Namenda off-label*").

allegation that falls short of establishing that Forest knowingly sought to induce actual false claims. *See, e.g.*, *Nowak*, 806 F. Supp. 2d at 357 (dismissing FCA claims where "[defendant] clearly intended to profit from off-label sales" but it was not clear "[defendant] intended to do so specifically at the expense of government coffers tapped to pay non-reimbursable claims"); *Worsfold*, 2013 WL 6195790, at *8–9 ("[M]ere allegations that a company intended to promote off-label uses and profit from such sales fails to demonstrate that [defendant] intended to do so at the government's expense."); *U.S. ex rel Pilecki-Simko v. Chubb Institute*, 443 F. App'x 754, 759–61 (3d Cir. 2011) (affirming dismissal of FCA claims where complaint included only conclusory allegations of defendants' knowledge of false claims).

Indeed, courts recognize that "physicians are not unsophisticated lay persons and it is reasonable to assume that they are familiar with relevant medical literature." *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 1:09–CV–1086 (AJT), 2011 WL 3911095, at *5 (E.D. Va. Sept. 6, 2011), *aff'd*, 707 F.3d 451 (4th Cir. 2013); *see also Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1362 (11th Cir. 2011) ("[W]hen a doctor prescribes a drug, he presumably does so only if, in the exercise of his independent medical judgment, he believes the drug will benefit his patient."); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04–CV–0704 (ERK), 2009 WL 1456582, at *7–8 (E.D.N.Y. May 22, 2009). As such, FCA complaints premised on off-label promotion typically are successful only if they "involve allegations that the judgment of a physician was altered or affected by the defendant's fraudulent activities, which . . . typically involve improper payments, benefits or inducements, or misrepresentations." *Nathan*, 2011 WL 3911095 at *5.[17]

[17] *See also U.S. ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 398–400 (D. Mass. 2010) (including allegations of kickbacks, misrepresentations, and presentation of studies supporting off-label use); *U.S. ex rel. Franklin v. Parke–Davis*, 147 F. Supp. 2d 39, 45–46 (D. Mass. 2001) (including allegations of kickbacks, provision of false information relating to safety and efficacy, and

The SAC is devoid of any allegation that Forest's alleged off-label marketing interfered with physicians' independent medical judgment. Relator does not allege that Forest misrepresented scientific literature, FDA approval status, or otherwise contaminated the well of medical knowledge. *See, e.g., U.S. ex rel. Bennett v. Boston Scientific Corp.*, No. H–07–2467, 2011 WL 1231577, at *11 (S.D. Tex. Mar. 31, 2011) (dismissing FCA claims where "there [was] no allegation that defendants concealed or misstated the limits of the FDA's approval").[18] Nor does the SAC allege that Forest paid kickbacks or otherwise offered any incentives—financial or otherwise—to physicians to write off-label prescriptions of Namenda.[19]

To the contrary, the SAC asserts that each of the eight physicians who prescribed Namenda for mild AD *knew* the use was off-label and not approved by the FDA. SAC ¶¶ 94, 103, 113, 121, 128, 136, 145, 154. Simply alleging in conclusory fashion that these physicians "relied" on Forest's off-label promotion in some unknown way is insufficient to establish that Forest knowingly caused the submission of a false claim, particularly absent any allegation that the physicians were misled in any way, that the purported off-label messages were material to their decision to prescribe the drug, or that they would not have otherwise prescribed it in the absence of the messages. *See, e.g., Worsfold*, 2013 WL 6195790, at *8 (dismissing FCA claims premised on assumption that any off-label prescription was "necessarily caused by [off-label promotion]" and not simply the "result of that physician's exercise of his or her independent

misrepresentations regarding credentials); *Strom ex rel. United States v. Scios. Inc.*, 676 F. Supp. 2d 884, 888–89 (N.D. Cal. 2009) (noting relator alleged defendants hired ghostwriters to draft and submit articles favorable to drug while attributing work to doctors and nurses); *In re Pharm. Industry Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 373–74 (D. Mass. 2008) (explaining that relator alleged defendant paid "cash bribes" to hospitals to induce false claims).

[18] *Cf. Franklin*, 147 F. Supp. 2d at 145–46 (denying motion to dismiss in light of efforts to conceal lack of FDA approval, misrepresent clinical data, and present sales representatives as scientific experts).

[19] *Cf. U.S. ex rel. Bergman v. Abbot Labs.*, No. 09–4264, 2014 WL 348583, at *12 (E.D. Pa. Jan. 30, 2014) (denying motion to dismiss where allegations were explicitly "linked to the illegal kickbacks made to physicians as a means for inducing the physicians to prescribe [drug] for off-label uses").

judgment"); *Nathan,* 2011 WL 3911095 at *5 (dismissing FCA claims absent allegations of kickbacks, improper incentives, or efforts to distort medical literature); *cf. U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570MLM, 2006 WL 1064127, at *7–9 (E.D. Mo. Apr. 21, 2006) (rejecting conclusory allegations that providing immature study information caused false claims).[20]

C. THE CONSPIRACY CLAIM FAILS

Finally, the FCA conspiracy claim fails for multiple reasons. ***First***, failure to plead an underlying FCA claim is fatal to Relator's conspiracy claim. *See, e.g., Vigil*, 639 F.3d at 801; *U.S. ex rel. Rector v. Bon Secours Richmond Health Corp.*, No. 3:11–CV–38, 2014 WL 1493568, at *12 (E.D. Va. Apr. 14, 2014); *U.S. ex rel. Phillips v. L-3 Commc'n. Integrated Sys. L.P.*, No. 3:10–CV–1784–L, 2012 WL 3649699, at *8 (N.D. Tex. Aug. 24, 2012).

Second, Relator fails to plead an FCA conspiracy with the requisite particularity. *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (holding FCA conspiracy claims must be pleaded in accordance with Rule 9(b)). The SAC's conclusory allegation that "Defendants combined, conspired, and agreed together with physicians and others to defraud the United States" is wholly insufficient. SAC ¶ 218. The SAC is devoid of allegations establishing the basic elements of a conspiracy, such as the members of the conspiracy,[21] an agreement

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[20] Nor does the SAC allege that Forest or its agents attempted to coach prescribers or pharmacists on how to conceal non-reimbursable prescriptions as legitimate claims for government payment. *See, e.g., Nowak*, 806 F. Supp. 2d at 357 (dismissing claims where complaint did not allege facts supporting inference defendant intended false claims be filed); *cf. Franklin*, 147 F. Supp. 2d at 146 (denying motion to dismiss where defendant was alleged to have "coach[ed] doctors on how to conceal off-label nature of the prescription").

[21] The SAC does not identify any physicians or articulate how they conspired or agreed together with Defendants to defraud the government. The only identified members of the conspiracy are Defendants, who cannot by themselves form a conspiracy. *Rector*, 2014 WL 1493568, at *12 (dismissing FCA conspiracy claims where alleged conspirators were entities within same corporate structure); *U.S. ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 & n.17 (D. Md.

among those members, or specific intent to engage in a conspiracy, much less the details of the purported conspiracy with any particularity. *See, e.g., U.S. ex rel. McGinnis v. OSF Healthcare Sys.*, No. 11–CV–1392, 2014 WL 378644, at *7–8 (C.D. Ill. Feb. 3, 2014) (dismissing FCA conspiracy claim where no co-conspirators were identified); *U.S. ex rel. Estate of Cunningham v. Millennium Labs. Of California*, No. 09–12209–RWZ, 2014 WL 309374, at *1–2 (D. Mass. Jan. 27, 2014) (dismissing FCA conspiracy claims absent allegation of an agreement); *U.S. ex rel. DeCesare v. America In Home Nursing*, 757 F. Supp. 2d 573, 584 (E.D. Va. 2010) (dismissing FCA conspiracy claim absent allegations of an agreement, scienter, and membership).

IV. CONCLUSION

For all of the foregoing reasons, Defendants respectfully request that the Court dismiss the SAC in its entirety and with prejudice pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b).

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Respectfully submitted,

/s/ Mark P. Goodman

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2006) (same); s*ee also Copperweld Corp. v. Independence Tube Corp.*, 467 U.S 752, 771–72 & n.19 (1984) (rejecting intra-corporate conspiracy).

CERTIFICATE OF SERVICE

I, J. Robert Abraham, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those attorneys still active indicated as non-registered participants on June 30, 2014.

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